DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

3821. Misbranding of male hormone tablets. U. S. v. 719 Boxes, etc. (F. D. C. No. 33331. Sample Nos. 34692–L, 34693–L.)

LIBEL FILED: July 19, 1952, Western District of Arkansas.

ALLEGED SHIPMENT: On or about May 29, 1952, by Captivante Laboratories, from New York, N. Y.

PRODUCT: 1,3[illegible] 60-tablet boxes of *male hormone tablets* at Hot Springs, Ark.

LABEL, IN PART: (Box) "Yale Testrex Male Sex Hormones 60 Tablets * * * Ingredients per tablet 2.5 mg. Methyl Testosterone with Ethinyl Estradiol .0025 mg." and "Yale Testrex Male Sex Hormones 60 Tablets—Super-Strength (Double Potency) * * * Ingredients per tablet 5 mg. Methyl Testosterone with Ethinyl Estradiol .0050 mg."

NATURE OF CHARGE: Misbranding, Section 503 (b) (4), the tablets were intended for use by man and were subject to Section 503 (b) (1) (B), and the labels of the tablets failed to bear the statement "Caution: Federal Law prohibits dispensing without prescription."

DISPOSITION: September 23, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3822. Misbranding of dextro-amphetamine sulfate tablets, phenobarbital tablets, methyltestosterone tablets, and methamphetamine hydrochloride tablets. U. S. v. Glenn M. Stinson (Stinson Drug Store), and Floyd L. Yarbro. Pleas of nolo contendere. Glenn M. Stinson fined $205 and Floyd L. Yarbro fined $60. (F. D. C. No. 32727. Sample Nos. 15509–L to 15511–L, incl., 15513–L, 15514–L, 15520–L, 15523–L.)

INFORMATION FILED: September 18, 1952, Western District of Oklahoma, against Glenn M. Stinson, trading as the Stinson Drug Store, Lawton, Okla., and Floyd L. Yarbro, pharmacist.

INTERSTATE SHIPMENT: Prior to the dates of the sales reported below, various quantities of *dextro-amphetamine sulfate tablets*, *phenobarbital tablets*, *methyltestosterone tablets*, and *methamphetamine hydrochloride tablets* were shipped in interstate commerce into the State of Oklahoma.

ALLEGED VIOLATION: On or about October 11, 13, 15, and 22, 1951, while the drugs were being held for sale at the Stinson Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and sold without physicians' prescriptions, which acts resulted in the repackaged drugs being misbranded.

Glenn M. Stinson was charged in each of the 7 counts of the information and Floyd L. Yarbro in 4 counts with causing the acts of repacking and sale of the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the *dextro-amphetamine sulfate tablets* were fabricated from two or more ingredients, and the label failed to bear the common or usual name of each active ingredient of the drug; and Section 502 (f) (2), the *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use of the drug in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: October 1, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $205 against Glenn M. Stinson and $60 against Floyd L. Yarbro.

3823. Misbranding of thyroid tablets, dextro-amphetamine sulfate tablets, methyltestosterone tablets, phenobarbital and mannitol hexanitrate tablets, and elixir phenobarbital and thiamine. U. S. v. James H. Ford (Ford's Drug Store), and Bruce R. Lucas. Pleas of nolo contendere. James H. Ford fined $220 and Bruce R. Lucas fined $90. (F. D. C. No. No. 32731. Sample Nos. 15534–L to 15536–L, incl., 15540–L, 15542–L, 15543–L, 15545–L, 15547–L.)

INFORMATION FILED: October 1, 1952, Western District of Oklahoma, against James H. Ford, trading as Ford's Drug Store, Lawton, Okla., and Bruce R. Lucas, a pharmacist.

INTERSTATE SHIPMENT: Prior to the dates of the sales reported below, various quantities of *thyroid tablets, dextro-amphetamine sulfate tablets, methyltestosterone tablets, phenobarbital and mannitol hexanitrate tablets,* and *elixir phenobarbital and thiamine* were shipped in interstate commerce into the State of Oklahoma.

ALLEGED VIOLATION: On or about October 11, 13, 15, and 22, 1951, while the drugs were being held for sale at the Ford's Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and sold without physicians' prescriptions, which acts resulted in the repackaged drugs being misbranded.

James H. Ford was charged in each of the 8 counts of the information and Bruce R. Lucas in 6 counts with causing the acts of repacking and sale of the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (b) (1), with the exception of the *elixir phenobarbital and thiamine* and one sale of *methyltestosterone tablets*, the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (f) (1); the labeling of the drugs failed to bear adequate directions for use; and, Section 502 (e) (2), the *dextro-amphetamine sulfate tablets* were fabricated from two or more ingredients, and the label failed to bear the common or usual name of each active ingredient of the drug.

Further misbranding, Section 502 (d), the *phenobarbital and mannitol hexanitrate tablets* and the *elixir phenobarbital and thiamine* contained a chemical